IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA	:	
***ex rel.* DONALD R. GALMINES, et al.,**	:	**CIVIL ACTION**
Plaintiffs,	:	
	:	
v.	:	
	:	
NOVARTIS PHARMACEUTICALS CORPORATION,	:	**No. 06-3213**
Defendant.	:	

M E M O R A N D U M

PRATTER, J. FEBRUARY 27, 2015

Mr. Galmines brings this *qui tam* action against Novartis Pharmaceuticals Corporation ("Novartis") under the False Claims Act, 31 U.S.C. §§ 3729, et seq., and the laws of several states. Mr. Galmines asserts that Novartis engaged in "off-label" marketing for the drug Elidel, encouraging physicians to prescribe Elidel for purposes for which the FDA had not approved Elidel.[1] This marketing campaign resulted in submissions to the Government of false claims for reimbursement for the unapproved prescriptions of Elidel, including Medicare and Medicaid. Mr. Galmines also alleges that Novartis violated state "anti-kickback" statutes by providing various rewards to physicians who prescribed high volumes of Elidel.

The Court now must consider Mr. Galmines's Motion for Leave to File a Fourth Amended Complaint (Doc. No. 106). The need or at least the stated justification for the request for this Fourth Amended Complaint allegedly arises out of a February 2014 discovery dispute between the parties. Mr. Galmines sought discovery relating to Novartis's conduct following the

[1] Specifically, Mr. Galmines alleges that Novartis marketed Elidel, an eczema drug, for unapproved uses such as first-line use, infant use, preventive use, and continuous use.

filing of the initial complaint on July 21, 2006. Novartis opposed this discovery request, and the Court ruled that, in order to obtain discovery for conduct after the date of the filing of the initial complaint, Mr. Galmines would need to allege wrongful conduct continuing after July 21, 2006. *See* Feb. 26, 2014 Order (Doc. No. 104). Mr. Galmines now seeks leave to file a Fourth Amended Complaint that alleges continuing wrongful conduct by Novartis through at least 2009. Novartis opposes permitting Mr. Galmines to amend his complaint a fourth time. Novartis argues that Mr. Galmines unduly delayed in proposing this amendment and that, in any case, the amendment is futile. Specifically, Novartis argues that the amendment is futile not only because the new allegations are not well-pleaded, but also because Mr. Galmines is not an "original source" of the publicly disclosed allegations, which status would bar his claims under the False Claims Act. The Court disagrees, however, and will allow Mr. Galmines file a Fourth Amended Complaint.

I. The Public Disclosure Bar and Original Source Exception

The primary point of contention among the parties is whether Mr. Galmines must meet the "original source" requirements for the new allegations and, if so, whether he does meet those requirements. The False Claims Act allows citizens to sue those making false claims to the federal government, though it bars such actions that are "based upon the public disclosure of allegations . . . unless . . . the person bringing the action is an original source of the information." *See* 31 U.S.C. § 3730(e)(4)(A) (2006).[2] The statute further defines "original source" as an individual who: (i) "has direct and independent knowledge of the information on which the allegations are based;" and (ii) has "voluntarily provided the information to the Government

[2] Although the Patient Protection and Affordable Care Act amended this portion of the False Claims Act, the amendment is not retroactive. *See Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson,* 559 U.S. 280, 283 n.1 (2010).

before filing an action under this section which is based on the information." *See* 31 U.S.C. § 3730(e)(4)(B). The Court has already determined that Mr. Galmines is an original source of the off-label marketing and kickback schemes in operation when he worked at Novartis, allowing him to bring his lawsuit even though his allegations are based upon publicly disclosed information. The Court must now consider whether the new proposed allegations are barred because they are likewise based on public disclosures and because Mr. Galmines is *not* an original source of these new allegations, even though he *was* an original source of the earlier allegations.

The Court has already grappled with the original-source exception to the public-disclosure bar in this case. In June of 2013, the Court held that Mr. Galmines could qualify as an original source under the False Claims Act even though his direct and independent knowledge concerned only Novartis's practices that *caused* the false claims and not the false claims themselves. *See generally* June 13, 2013 Memorandum (Doc. No. 68) *available at* 2013 WL 2649704. The Court found this case to be distinguishable from the Third Circuit Court of Appeals's opinion in *United States ex rel. Mistick PBT v. Housing Authority*, 186 F.3d 376 (3d Cir. 1999), in which the Third Circuit Court of Appeals held that a relator was not an original source where the relator lacked direct and independent knowledge of the defendant's false submissions to the Government, "the most critical element of its claims." *See id.* at 388. The Court determined that because the allegations of Mr. Galmines are merely that Novartis *caused* others to submit false claims and did not submit false claims itself, the ruling in *Mistick* did not apply. The False Claims Act does allow claims where the defendant only "causes to be presented" a false claim, *see* 18 U.S.C. § 3729, and for such claims, the "most critical element of

[the] claims" is not the submission to the Government but the conduct causing the false submissions.

a. Public Disclosures

The parties dispute whether the new allegations are based upon public disclosures. The Court agrees with Novartis that they are. Mr. Galmines argues that "[m]any details in Mr. Galmines [sic] Fourth Amended Complaint were provided by Novartis in non-public documents to the U.S. [A]ttorney in the Eastern District of Pennsylvania and/or the state of Texas in response to Civil Investigative Demands." Mot. at 6. However, Novartis points out that Mr. Galmines has already conceded that the fraudulent scheme underlying his claims were publicly disclosed. *See* Mem. in Opposition 8 (citing Relator's Response in Opposition to Mot. to Dismiss 26-27 (Doc. No. 45)). The question, then, which resonates throughout this present procedural dispute, is whether it is correct to conclude that because the original claims were based on public disclosures, the new allegations are also based on those same public disclosures. To answer this question, the Court has to consider whether the new allegations are "substantially similar" to those which have been publicly disclosed. *U.S. ex rel. Paranich v. Sorgnard*, 396 F.3d 326, 334-35 (3d Cir. 2005). Here, they are substantially similar, as they allege the same underlying scheme, but as applied to a new time period. *See id.* at 335 ("[A] *qui tam* action is 'based upon' a qualifying disclosure if the disclosure sets out either the allegations advanced in the *qui tam* action or all of the essential elements of the *qui tam* action's claims." (citation omitted)); *cf. U.S. ex rel. Tahlor v. AHS Hosp. Corp.*, No. 2:08-02042, 2013 WL 5913627, at *8 (D.N.J. Oct. 31, 2013) ("Finally, a claim can be 'based upon' a public disclosure if the public disclosure concerned similar conduct that occurred in a different time period."). Therefore, the Court finds

that the public disclosure bar applies to the new allegations, and Mr. Galmines will need to qualify as an original source for these new allegations.

b. Original Source

This leads to the crux of this dispute—is Mr. Galmines an original source of the allegations that Novartis continued to unlawfully market Elidel after the filing of the original complaint in this case? Although it is a close question with little law on point, the Court holds that because Mr. Galmines is an original source of the underlying scheme, he is also an original source of these additional allegations that the same underlying scheme is continuing.

Novartis asserts that Mr. Galmines does not have direct and independent knowledge of any unlawful conduct relating to the marketing of Elidel after he left Novartis's employ in May 2006, and that he is not, therefore, an original source of the new allegations. This, Novartis asserts, should prevent Mr. Galmines from amending his complaint to allege that the underlying scheme continued after his employment at Novartis ended. Defendant relies primarily on three cases in support. Novartis would have the Court read a strict time limitation into the original source exception, such that a relator's status as an original source begins and ends strictly when her direct and independent knowledge begins and ends. However, such a reading comports neither with the law nor the policy behind the False Claims Act.

While there is no controlling Third Circuit case law directly on point, the Court perceives some guidance from the language of the Third Circuit Court of Appeals in *Mistick*, in which the court held that a qui tam plaintiff must have "direct and independent knowledge of the most critical element of its claims," but "it is not necessary for a relator to have all the relevant information in order to qualify as independent." 186 F.3d at 388-89 (quotation marks and citations omitted); *see also* June 13, 2013 Memorandum *available at* 2013 WL 2649704, at *9

("Here, however, the centerpiece of Mr. Galmines's claim is Novartis's off-label marketing and kickback scheme. Given that Mr. Galmines has direct and independent knowledge of that scheme, and bearing in mind that Third Circuit appellate precedent does not require Mr. Galmines to have firsthand knowledge of 'all the relevant information' on which his allegations are based, the Court holds that Mr. Galmines is an original source and that the [False Claims Act's] public disclosure bar does not prohibit his suit." (citation omitted)). In other words, a relator's allegations need not be strictly limited to the information as to which she has direct and independent knowledge, provided that the relator has direct and independent knowledge of the critical elements of the alleged fraudulent scheme. The precise start and end dates of a fraudulent scheme are not "critical elements" of a False Claims Act claim. *See U.S. ex rel. Judd v. Quest Diagnostics Inc.*, No. 10-4914, 2014 WL 2435659, at *8 (D.N.J. May 30, 2014) ("Indeed, time, place, and manner allegations do not, in themselves, constitute the essential elements of a fraudulent scheme."). The precise duration of a fraudulent scheme goes not to liability but to damages—and not even to the existence of damages, but to the quantum of damages. *Cf. Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 114 n.9 (1969) ("Zenith's burden of proving the fact of damage . . . is satisfied by its proof of some damage flowing from the unlawful conspiracy; inquiry beyond this minimum point goes only to the amount and not the fact of damage."). One would expect that a relator with direct and independent knowledge of the critical elements of the fraud might not know when the fraudulent scheme began or ended, and it would make little sense not to allow a relator to obtain these details during discovery and amend her complaint accordingly.

Contrary to Novartis's contention, the Supreme Court's decision in *Rockwell International Corp. v. United States*, 549 U.S. 457 (2007), does not stand for the proposition that

the scope of a relator's claim as an original source against his former employer extends only to the date when the relator's employment ended. In *Rockwell*, the plaintiff-relator, an engineer named Mr. Stone, worked for six years at Rockwell before he was laid off in 1986. *Id.* at 460-61. Rockwell was, at the time Mr. Stone worked there, exploring a process for creating pondcrete (a mixture of cement and toxic pond sludge), which would be used to complete its obligations under a contract with the Department of Energy.[3] *Id.* at 461. Mr. Stone reviewed Rockwell's plans and expressed concerns that the piping system proposed to remove the sludge from the pond would be inadequate, causing a poor mix of pondcrete that would easily disintegrate. *Id.* Rockwell nevertheless pushed forward with its pondcrete project. *Id.* As it turns out, the pondcrete blocks lacked integrity, and they leaked the toxic pond sludge into the ground. *Id.* at 462. Rockwell did not reveal this to the Department of Energy, which continued to pay Rockwell based on the premise that Rockwell was meeting the Government's environmental standards for the project. *Id.* The Supreme Court considered whether Mr. Stone could be an original source of the allegations that Rockwell was creating leaky pondcrete. The Supreme held that Mr. Stone was not an original source of these allegations "[b]ecause Stone was no longer employed by Rockwell at the time, he did not know that the pondcrete storage was even subject to RCRA; he did not know that Rockwell would fail to remedy the defect; he did know that the insolid pondcrete leaked while being stored onsite; and, of course, he did not know that Rockwell made false statements to the Government regarding pondcrete storage." *Id.* at 476. The Court further reasoned that "[e]ven if a prediction can qualify as direct and independent knowledge in some cases (a point we need not address), it assuredly does not do so when its premise of cause and

[3] Essentially, the pond sludge was contaminated and Rockwell had a contract to dispose of it, which it planned to do by creating "concrete-hard" pondcrete which could be moved and stored more effectively. *Id.* at 461.

effect is wrong. . . . As Stone acknowledge, Rockwell was able to produce 'concrete hard' pondcrete using the machinery Stone said was defective. According to [Stone's] allegations in the final pretrial order, the insolidity problem was caused by a new foreman's reduction of the cement-to-sludge ration in the winter of 1986, long after Stone had left [Rockwell]." *Id.* at 475-76.

The holding in *Rockwell* was not—as Novartis contends—that the relator categorically could not be an original source for any allegations extending past the date of his employment. Rather, the Court held merely that the relator had no direct and independent knowledge of the facts underlying the fraudulent *scheme*. *See U.S. ex rel. Hockett v. Columbia/HCA Healthcare Corp.*, 498 F. Supp. 2d 25, 54 (D.D.C. 2007) ("Under *Rockwell*, a relator must qualify as an original source for each distinct kind of claim or scheme she alleges."). The relator predicted that the pondcrete would fail for one reason, then the relator was laid off, and then the pondcrete failed—but for an entirely different reason than the one the relator had predicted. Here, Mr. Galmines observed the off-label marketing and illegal kickbacks firsthand, then he left Novartis and filed this lawsuit, but the off-label marketing and illegal kickbacks continued as they had before he left Novartis. The analogous situation would have been if the relator in *Rockwell* observed the pondcrete failing, then brought a lawsuit and then left Rockwell, and the pondcrete continued to fail for the same reason the relator alleged in his lawsuit. Barring the relator in such a scenario from bringing a claim for the entire fraudulent scheme would not comport with common sense, the general principles of law, or the scheme of the False Claims Act. The key distinction in *Rockwell* was the fact that the relator had no direct and independent knowledge of the material facts underlying the actual fraudulent scheme—not that he was no longer employed at the company allegedly perpetrating the fraud. *Cf. U.S. ex rel. Repko v. Guthrie Clinic, P.C.*,

No. 3:04-1556, 2011 WL 3875987, at *16 (M.D. Pa. Sept. 1, 2011) (declining to allow the relator to pursue claims relating to a time period after the relator's period of employment with the alleged perpetrator of the fraud, as the new claims "*changed* and began to echo material widely available and publicly disclosed" (emphasis added)).

However, there are at least two cases that appear to come to the contrary conclusion. A 2013 District of New Jersey case, *Tahlor*, did hold that:

> Relators might argue that they are original sources with respect to their Post-July 31, 2009 OMC Claims since Relators are the original source of information about what happened at OMC when Relators were still employed by AHS. . . . The Public Disclosure Bar is meant to promote private citizen involvement in exposing fraud against the government, while at the same time prevent parasitic suits by opportunistic late-comers who add nothing to the exposure of the fraud. The Post-July 31, 2009 OMC claims add nothing to the exposure of fraud because the Settlement between AHS and the Government put the Government on notice that allegedly improper [fraudulent] conduct was occurring at OMC.

2013 WL 5913627, at *11 (quotation marks and citations omitted).

The Court here does not reach the same conclusion as the *Tahlor* court. For one, the *Tahlor* court provides little explanation for its conclusion that the relators could not pursue alleged fraudulent conduct that occurred post-termination, even though the conduct emanated from the same fraudulent scheme. This suggests to the Court that the context in *Tahlor* partially drove the outcome, given that since the Government had settled the claims for the time period during which the relators had been employed, the relators' services in pursuing the later time period would be of little use since their direct and independent knowledge went *exclusively* to a time period that was no longer at issue (unlike here where Mr. Galmines is not exclusively pursuing conduct that occurred after he left Novartis). Additionally, the *Tahlor* court appears to have concluded that, after several years of litigation and a settlement, allowing the case to reopen as to new allegations for a scheme for which the Government had already reached a settlement

would not serve the purposes of the False Claims Act. Here, however, there has been no settlement with the Government—the allegations about the scheme remain active. Thus, the Court does not find the result in *Tahlor* to be persuasive for the facts of this case.

A District of Massachusetts court concluded in *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, No. 03-12189, 2010 WL 3810858, at *2-3 (D. Mass. Sept. 27, 2010), that a relator could only serve as an original source for the period of time during which he was employed by the defendant and that the relator would be limited in recovery to that discrete period. The Court is not persuaded by *Duxbury*, however. At least one commentator has discussed and criticized *Duxbury*, arguing that "once the 'original source' status of a relator is confirmed, the issue should not thereafter be used to limit the relator from fully investigating and fully recovering for all of the defendant's fraudulent conduct. . . . Nothing in the [False Claims Act] or its legislative history authorizes [the result in *Duxbury*]. No other court has since followed this approach, so it may well be an isolated occurrence of misapplication of the [False Claims Act]." James B. Helmer, Jr., False Claims Act: Whistleblower Litigation 410 (6th ed. 2012). The Court agrees with the commentator that the line drawn in *Duxbury* is untenable. Courts typically permit relators, once they have qualified as an original source for a fraudulent scheme, to pursue the full extent of that particular scheme. For example, the language of the First Circuit Court of Appeals when considering *Duxbury* on appeal offered the following:

> The district court was not required to expand the scope of discovery based upon the amended complaint's bald assertions that the purported kickback scheme continued after Duxbury's termination or that it was "nationwide" in scope. Nor did our holding in *Duxbury I* obligate the district court to do so. Rather, the district court limited discovery to those allegations, contained in paragraph 211 of the amended complaint, which satisfied Rule 9(b)'s particularity requirement. That result was entirely consistent with the district court's "considerable latitude" in assessing the proper scope of discovery, and did not amount to an abuse of discretion.

> At the close of the initial discovery period, Duxbury stipulated that she had not uncovered a single piece of admissible evidence to support any of her remaining Count I claims, let alone evidence to support her contention that OBP had orchestrated a "multi-year nationwide scheme" of kickbacks. Thus, this was not a case in which evidence was discovered of a nationwide scheme, which might then have been the basis for widening discovery.
>
> In light of this stipulation, the district court acted within its discretion in declining to issue Duxbury license to undertake a "fishing expedition" into the amended complaint's purely speculative allegations of fraud through further discovery.

U.S. ex rel. Duxbury v. Ortho Biotech Products, L.P., 719 F.3d 31, 39 (1st Cir. 2013) (citations omitted). This language implies that, when determining the extent to which an original source can allege and seek discovery for additional aspects of the same underlying scheme, the limiting principle is the sufficiency of the allegations and the evidence—not the ability of the relator to demonstrate that she has direct and independent knowledge of the extent of the fraudulent scheme. *See id.* ("Thus, this was not a case in which evidence was discovered of a nationwide scheme, which might then have been the basis for widening discovery."); *see also U.S. ex rel. Rost v. Pfizer, Inc.*, 253 F.R.D. 11, 17 (D. Mass. 2008) (holding that where an original source of a fraudulent scheme had only provided particularity as to false claims in Indiana, "the Court will permit discovery only relating to the sales and marketing region that includes Indiana. If the discovery shows that kickbacks were paid to the doctors who then made off-label prescriptions, and that this sales region was following national directives, the Court will expand the scope of discovery nationwide."). This principle should apply with equal force to the factor of time—the limitation on a relator's ability to recover for additional periods of time is not the original source bar but the pleading requirements and the discretionary powers of the court over discovery.

The applications of the public disclosure bar and the first-to-file rule demonstrate just how extraordinary a position it would be for the Court to adopt Novartis's proposal. Courts, when considering whether a case is based upon allegations that have been publicly disclosed,

regularly conclude that a plaintiff is barred from bringing a lawsuit alleging the same scheme as that which was publicly disclosed, but for a different time period. *See, e.g.*, *Judd*, 2014 WL 2435659, at *8 ("[N]ot a single circuit has held that a *complete* identity of allegations, even as to time, place, and manner is required to implicate the public disclosure bar. Indeed, time, place, and manner allegations do not, in themselves, constitute the essential elements of a fraudulent scheme. . . . Thus, allegations of different time periods of virtually the same scheme do little to take away from their similarity under the public disclosure bar." (citations omitted)); *Tahlor*, 2013 WL 5913627, at *8 ("Finally, a claim can be 'based upon' a public disclosure if the public disclosure concerned similar conduct that occurred in a different time period.").

More problematic, the first-to-file rule, which provides that "[w]hen a person brings [a qui tam action], no person other than the Government may intervene or bring a related action based on the facts underlying the pending action," 31 U.S.C.A. § 3730(b)(5), has also been interpreted to bar lawsuits based on the same essential facts but different time periods. *See, e.g.*, 10A Fed. Proc. Forms § 34:550 ("If the later-filed complaint alleges the same type of wrongdoing as the first, therefore, and the first adequately alleges a broad scheme encompassing the time and location of the later filed, the fact that the later complaint describes a different time period or geographic location that could theoretically lead to a separate recovery does not save it from the [False Claims Act's] absolute first-to-file bar."). The purpose of this broad interpretation of the first-to-file bar is multifold. For one, it "encourage[es] *qui tam* plaintiffs to report fraud promptly." *U.S. ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc.*, 149 F.3d 227, 234 (3d Cir. 1998). "Also, as a matter of fairness claimants alleging the same material facts as prior relators should not share in a *qui tam* award, because their allegations are unlikely to increase the total recovery. In addition, such duplicative claims do not help reduce fraud or

return funds to the federal fisc, since once the government knows the essential facts of a fraudulent scheme, it has enough information to discover related frauds." *Id.* The first-to-file bar has also applied to bar suits relating to conduct occurring after the filing of the original complaint where, as here, a relator merely alleges that a particular scheme is continuing or ongoing. *See U.S. ex rel. Chovanec v. Apria Healthcare Group, Inc.*, 606 F.3d 361, 365 (7th Cir. 2010) (Easterbrook, J.).

The implication of these broad interpretations of the public disclosure and first-to-file rules is twofold. First, in interpreting whether the time period of the alleged fraud is a "critical element" of which an original source must have direct and independent knowledge, a court can reason by analogy and conclude that it is not a critical element, but rather part of the "relevant information" of which a relator need not have direct and independent knowledge of every detail. After all, if the time period of the fraud is not a "material fact" for purposes of the first-to-file rule, it would bedevil judicial reasoning to conclude it is nonetheless a critical element for original-source purposes.

Second, because of the broad interpretations of the public disclosure and first-to-file rules, if the Court were to interpret that a relator need direct and independent knowledge as to the entire time period alleged, there might well be a situation where no relator can bring a lawsuit for a certain time period of fraud. This would be because the original source who filed first might lack direct and independent knowledge of a later time period (perhaps of the fraud that continued after the filing of the complaint), but no other relator can bring a lawsuit because they will be barred under the first-to-file rule, even if they do have direct and independent knowledge of later fraud.

Consider the hypothetical of a woman who starts work at a hospital and, on her first day of work, obtains direct and independent knowledge of every critical element of a scheme to defraud the Government (admittedly a tall premise). After only the one day of work, this woman quits her job and sues under the False Claims Act. But, it turns out, this fraud had been going on for 10 years and was publicly disclosed in a newspaper story the day before this woman began work. Under Novartis's interpretation of the original source requirement, (a) this woman can sue for only the one day of fraud for which she has direct and independent knowledge; and (b) no other putative relator could sue for the rest of the time period of this fraudulent scheme, because they would be barred under the first-to-file and public disclosure rules. Is this result consistent with the scheme of the False Claims Act's public disclosure and original source requirements? What public policy is served by such a result? Why should the potential for mischief to benefit a potential wrongdoer be embraced by the rule Novartis seeks?

To address these questions, the Court needs to consider the policy behind these provisions. As the Third Circuit explained in *LaCorte*, "The 1986 amendment, which introduced the current version of section 3730(b)(5), sought to achieve the golden mean between adequate incentives for whistle-blowing insiders with genuinely valuable information and discouragement of opportunistic plaintiffs who have no significant information to contribute of their own. In construing section 3730, we are mindful of the need to preserve a balance between the amendment's two competing goals." 149 F.3d at 234 (quotation marks and citation omitted).

Thus, the Court must balance these two goals in construing the original source requirement: (a) preventing parasitic lawsuits; and (b) providing adequate incentives for whistle-blowing insiders with valuable information to bring qui tam actions. The Court concludes that the position that strikes the best balance between those competing goals is to allow original-

source relators to pursue the entire fraudulent scheme for which they have direct and independent knowledge of the operative substantive facts, and not to limit relators to the specific time periods for which they have direct and independent knowledge, particularly where the relator has alleged the scheme was "continuing" as of the day they lost their direct and independent knowledge by reason of a cessation of employment or equivalent development. This interpretation of the original-source requirement does little to encourage parasitic lawsuits, since only the first-to-file can bring a qui tam suit for the scheme. True, this interpretation allows a relator to recover for a period of time for which she does not have direct and independent personal knowledge, making her perhaps less helpful as a qui tam plaintiff, but where the choice is between having no relator and having a relator with direct and independent knowledge as to the essential elements of the underlying scheme, if not all its tertiary details, the latter choice best comports with the policy of the False Claims Act. Further, this interpretation encourages insiders to bring qui tam actions. Not only is the potential recovery greater, but the incentive is to bring a qui tam lawsuit immediately, rather than to wait until the scheme has concluded, which delay might well ensue to allow for greater potential recovery if recovery were limited to those time periods for which the relator had direct and independent knowledge. Finally, adopting Novartis's interpretation would give those who defraud the Government an incentive to (a) fire whistleblowers immediately; and (b) once the first complaint has been filed and the initial complainer fired, continue engaging in the fraudulent conduct, knowing that no relator can bring a qui tam lawsuit for the time period for which the original source lacks direct and independent knowledge.[4]

[4] The Government would still be able to bring a lawsuit for the time period for which the relator lacks direct and independent knowledge, but the purpose of the qui tam provision in the False Claims Act is to allow a relator to sue on behalf of the Government. If the Government will need to intervene in every qui tam action to cover the entire time period of fraudulent activity, the purposes of the qui tam provision will largely be defeated.

Here, Mr. Galmines should qualify as an original source for the entire fraudulent scheme to market Elidel off-label and provide illegal kickbacks, even if that scheme extended past his dates of employment or continued past the date of the filing of his complaint. Mr. Galmines alleged that this same operative fraudulent scheme was continuing when he filed his complaint, and his proposed amendments merely provide sufficiently pleaded allegations of the fact that the scheme has continued past the date of the filing of the original complaint.[5] Not allowing him to amend his complaint could also allow Novartis to escape liability for any related fraud that occurred after the filing of this lawsuit, as the Government has thus far declined to intervene and all other potential relators would be barred under the first-to-file rule. Such a result does not comport with the law or policy of the False Claims Act.[6]

II. Pleading Requirements

Just because Mr. Galmines qualifies as an original source for the entire scheme does not mean he can obtain discovery *ad infinitum*. Rather, he must meet the pleading requirements and sufficiently allege that the scheme occurred past the date of his filing of his complaint. *See* Feb. 25, 2014 Order (requiring plaintiff to submit "a Proposed Fourth Amended Complaint with well-pleaded factual allegations sufficient to show that Novartis's alleged wrongful conduct continued after July 21, 2006, as well as more specific timeframes for those allegations currently alleging that conduct occurred 'to the present' or were otherwise made out in the present tense."). By requiring Mr. Galmines to amend his complaint in order to obtain discovery for the conduct

[5] Moreover, Mr. Galmines had direct and independent knowledge that, as of the date his employment at Novartis ended, the scheme was ongoing. In this context, he should be permitted to pursue the scheme to the extent that it continued.

[6] The original source exception also requires that Mr. Galmines disclosed his knowledge to the Government before filing suit. The Court agrees with the position of the United States that because Mr. Galmines has met this requirement with respect to the ongoing scheme alleged in his original complaint, such a disclosure is not required for these supplements to his original allegations.

occurring after he filed his complaint, the Court sought to ensure both that the pleading requirements would be satisfied and that there was some basis in fact for allowing discovery for the newly alleged time period—the Court did not intend to charter a fishing expedition. Mr. Galmines has both satisfied the pleading requirements and adequately addressed the Court's concerns about the basis in fact for the new allegations.

Mr. Galmines has sufficiently alleged that the off-label marketing continued until at least April 2009 and the illegal kickbacks continued until at least mid-2007. His supplemental allegations include allegations about how Novartis instructed its employees to market Elidel off-label using a visual aid in 2007, *see* Proposed Fourth Am. Compl. ¶ 79, how the marketing of Novartis continued to be targeted at off-label uses beyond the date of the original complaint, *see, e.g.*, *id.* ¶ 83 (use of the phrase "steroid-free"), ¶ 103 (focus on sensitive skin messaging), ¶ 108 (website implicitly advocating use of Elidel as first-line treatment for eczema), ¶ 109 (availability of Eczema Survival Guide through March 16, 2008), how off-label uses of Novartis have continued through at least April 2009, *see id.* ¶ 128, and how Novartis continued to pay speaking fees to doctors who prescribed Elidel and to provide them with other kickbacks like golf trips, *see id.* ¶¶156-58. These new allegations, while perhaps not sufficient in isolation to adequately allege a violation of the False Claims Act, are, when considered together with the original allegations, sufficient to meet even the heightened requirements of Rule 9(b) and are sufficient to convince the Court that, by allowing the amendments, it is not encouraging unrestrained discovery.

III. Equitable Considerations

Finally, before allowing Mr. Galmines to amend (or "supplement") his complaint, the Court must consider whether the supplemental pleading should be denied because of undue delay

or bad faith. *Arthur v. Maersk, Inc.*, 434 F.3d 196, 204 (3d Cir. 2006). The touchstone of this analysis is prejudice to the defendant. *Id.*

Although it is a fair question whether Mr. Galmines's years of delay before supplementing his pleading with well-pleaded allegations as to the post-2006 conduct warrant a denial of his motion to amend, the Court concludes that the delay does not warrant denying leave to amend. Although a more diligent approach would have been to seek leave to amend immediately upon uncovering the underlying facts of the new allegations, the delay here was not undue or a result of bad faith. Mr. Galmines apparently believed that his bald assertions of "ongoing" conduct would allow for discovery past the date of the filing of the original complaint. While case law contradicts this view, the Court does not find that Mr. Galmines had a dilatory motive. Novartis argues that it will be prejudiced by a Fourth Amended Complaint, given the immense discovery costs it will have to incur given the expanded time period. But Novartis has not persuaded the Court that the delay itself has prejudiced Novartis. Of course more discovery will cost more money—that is a fundamental law of litigation. The appropriate inquiry is not whether it will be costly to defend against the allegations because of the nature of the allegations but whether the delay "impaired [Novartis's] ability to defend against the suit or that it was unfairly disadvantaged or deprived of the opportunity to present facts or evidence which it would have offered had the amendment been timely." *Id.* at 206 (quotation marks, alterations, and citation omitted). Here, Novartis's ability to defend against the suit has not been impaired because of the delay. Fact discovery in this case is ongoing and counsel for Mr. Galmines represented at oral argument that they would be ready to try this case at the same time whether or not the amendments are admitted. *See* Tr. of Jan. 22, 2015 Oral Argument 66:7-13. There is every reason to hold counsel to their word. The Court recognizes that additional discovery will

require additional work, additional hours, and additional expense but also that the new allegations raise no new claims and will involve many of the same documents and witnesses as the earlier allegations. Although all counsel should be frustrated that a case initiated in 2006 has yet to reach a resolution, the Court does not find that there has been *undue* delay warranting denial of the proposed amended complaint.

IV. Conclusion

For all the foregoing reasons, the Court will permit Mr. Galmines to submit a Fourth Amended Complaint. An order consistent with this Memorandum follows.

BY THE COURT:

S/Gene E.K. Pratter
GENE E.K. PRATTER
United States District Judge